

## **REMARKS**

Pursuant to 37 CFR § 1.114, Applicants submit the following amendment and remarks in addition to the fee set forth in 37 CFR § 1.17(e). Claims 17-59 and 61-73 were previously examined. Claims 17, 19-24, 26-59 and 63-73 were rejected. Claim 18 and 25 were objected to. Claims 61-62 were allowed. Claims 17-18, 23, 25, 29, 60, 66 and 68-73 are canceled. Claims 17-59 and 61-73 remain in the application. Claims 19, 21-22, 24, 26-28, 30, 33, 35, 38, 40, 44, 48, 54 and 64-65 are amended. Support for the amendments can be found in, for example, page 8 of the Application. As such, no new matter has been added.

Applicants express their appreciation to the Examiner for the allowance of claims 61-62.

Claims 18 and 25 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. New claims 74 and 75 are claims 18 and 25, respectively, written in independent form. Applicant respectfully requests allowance of claims 74 and 75.

Dependent claims 19-22 are dependent on allowable and independent claim 74 (or a dependent claim thereto) and Applicants respectfully request allowance thereof. Dependent claims 24 and 26-27 are dependent on allowable and independent claim 75 and Applicants respectfully request allowance thereof.

### **I. Claims Rejected Under 35 U.S.C. § 112**

A.

The Examiner has rejected Claims 24, 35, 29, 41, 54 and 63 under 35 U.S.C. §112, first paragraph, for failing, according to the Examiner, to meet the requirement of enablement. The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry: (1) how broad the claim is with respect to the disclosure and (2) if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation. MPEP 2164.08. First, the claims of which the Examiner rejects are actually *narrower* than the embodiments described in the specification.

Representatively, the second paragraph on page 18 states: “[i]n a preferred embodiment, **an inflatable balloon** is provided in the catheter for centering the source tip of the source wire.” (App., p. 18) The term “inflatable balloon” is generic to a balloon of specific design, e.g., a segmented, scalloped or channel balloon. That is, “inflatable” can mean capable of expanding and “balloon” can mean a body capable of expanding; the specific design of the balloon cannot be read into the generic term “inflatable balloon”. Accordingly, the claims of which the Examiner rejects are narrower than the embodiments described in the specification. Thus, an “inflatable balloon” with any specific design for centering a source tip of a source wire is commensurate in scope with the claims. Second, Applicants submit that, based on the description provided in the Application, one skilled in the art can make the claimed invention without undue experimentation. The Examiner admits that the specification is enabling for use of an inflatable balloon as a centering device. (Office Action, p.5) Thus, the specific design of the inflatable balloon is irrelevant because the specification is enabling as to a generic inflatable balloon. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP 2164. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

B.

Claims 64-73 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 66, 68-73 have been canceled, however, the limitations disclosed therein have been added to claims 28, 33, 38, 40, 44, 48 and 54, respectively. Amended claims 28, 33, 38, 40, 44, 48 and 54 include the limitation of “without dilating the lumen (or the duct or the vessel or said/the target site).” Although not explicitly disclosed in the specification, this function is an inherent feature of the segmented, scalloped, channeled or fluted balloon as disclosed in the subject claims. By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage without introducing prohibited new matter. MPEP 2163.07(a). The balloon disclosed in the specification includes inherent characteristics that prevent it from dilating a vessel wall. First, the balloon has less surface area with which to contact the wall of a vessel. That is, the balloon will only contact the vessel wall or the lesion at the lobed portions while allowing

perfusion of blood flow between the lobed portions. Second, once a lobed portion of the balloon makes contact with the vessel wall or lesion, that portion will stop inflating due to the resistance exerted by the vessel wall or lesion while the remaining lobes will continue to inflate due to the lack of pressure, i.e., no contact with the vessel wall or lesion, on the remaining lobes. As a result, the balloon becomes centered and does not dilate the vessel wall. In view of these inherent characteristics of the balloon, Applicants respectfully request withdrawal of the rejection.

## **II. Claims Rejected Under 35 U.S.C. § 103**

### **A.**

Claims 17, 19, 21-24, 27-41, 44-45, 46, 54, 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over German Patent No. G9,102,312.2 to Weigl (“*Weigl*”) in view of U.S. Patent No. 5,308,356 to Blackshear, Jr. et al. (“*Blackshear*”). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, the cited references do not teach or suggest all of the claim limitations of independent claims 28, 33, 38, 40, 44, 48 and 54. Amended claims 28, 33, 38, 40, 44, 48 and 54 include the limitations of “without dilating the lumen (or the duct or the vessel or said/the target site)” due to a channeled, fluted, scalloped or segmented centering balloon and/or catheter apparatus. By contrast, *Weigl* describes a device for the dilation of a blood vessel occlusion using a treatment catheter at whose tip a balloon is attached whose circumference can undergo a definite expansion. (*Weigl*, p. 2) *Weigl* does not teach or suggest a channeled, fluted, scalloped or segmented balloon for centering an irradiation tip without dilating the balloon vessel. *Blackshear* does not cure this lack of teaching or suggestion because *Blackshear* only discloses a pleated balloon member 16. (col. 5, lns. 29-32) Accordingly, Applicants respectfully submit that independent claims 28, 33, 40, 44 and 54 and their respective dependent claims are allowable over the cited references.

B.

Claims 48, 51-53, 57-58 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Weigl* in view of *Blackshear* in further view of U.S. Patent No. 4,881,937 to Van't Hooft et al. (*Van't Hooft*). Applicants submit that the cited references do not teach or suggest all of the claim limitations of independent claims 48 and 54. As discussed above, neither *Weigl* nor *Blackshear* disclose all of the claim limitations of independent claims 48 and 54. *Van't Hooft* does not cure this lack of teaching or suggestion because *Van't Hooft* only describes an apparatus for effecting radioactive therapy in an animal body. (Abstract) Accordingly, Applicants respectfully submit that independent claims 48 and 54 and their respective dependent claims are allowable over the cited references.

C.

Claims 20, 26, 42-43, 46, 49-50, 55-56 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Weigl* in view of *Blackshear* in further view of the Flexmedic article. Applicants submit that the cited references do not teach or suggest all of the claim limitations of independent claims 48 and 54. As discussed above, neither *Weigl* nor *Blackshear* disclose all of the claim limitations of independent claims 74, 75, 40, 44, 48 and 54. The Flexmedic article does not cure this lack of teaching or suggestion because the Flexmedic article only describes the use of Nitinol for guidewires. Accordingly, Applicants respectfully submit that independent claims 74, 75, 40, 44, 48 and 54 and their respective dependent claims are allowable over the cited references.

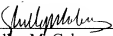
**CONCLUSION**

In view of the foregoing, it is believed that all claims now pending are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 500-4787.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP


Dated: November 29, 2006

  
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Shelley M. Cobos      Reg. No. 56,174

12400 Wilshire Boulevard  
Seventh Floor  
Los Angeles, California 90025  
(310) 207-3800

**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

  
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Si Vuong      November 29, 2006